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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/083,707 | 02/26/2002 | Gregory G. Brucker | S63.2-10308 | 1518 |

23552 7590 08/15/2006

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| EXAMINER |
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HO, UYEN T

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|-------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/083,707 | BRUCKER ET AL. | |
| | Examiner | Art Unit | |
| | (Jackie) Tan-Uyen T. Ho | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19, 39--61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19, 39-52 and 54-61 is/are rejected.
- 7) ☒ Claim(s) 45 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/06 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 17, 19, 39-44, 46-52, 54-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Vardi et al. (6,325,826).

Vardi et al. disclose a catheter with a single balloon (25) and the stent having structure and being made from material as claimed wherein the stent includes a first stent body (40) including a side opening and a plurality of members (38) moveably engaged to the stent wall (Figs. 7-10 & 13a-13f, col. 8 to col. 10, also see the detail

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description for the materials of the stent as claimed col. 9). Fig. 8 shows, the balloon (25) having an elongated body region and a bulge region at an end of body region which extends radially from the body region to enter the opening (16) so that the plurality of movable members positioned over the bulge region (fig. 8). Inherently, as the balloon expanded, the portion of the balloon 25 which extending through the opening 16 and expandable portion 38 is thinner (because of the stretching) than the rest of the balloon 25 which remains in the main stent 40. Fig. 7 shows, in the unexpanded condition the plurality of movable member (38) being retained substantially within the circumferential plane of the stent wall and in the expanded condition (fig. 8 and 9), the movable member (38) being extended radially outward from the stent wall to form a scaffold.

Regarding claim 17, the balloon 25 adapted to expand the stent body as it expanded within the stent wall.

Regarding claims 39, Vardi et al. disclose the stent being formed from shape-memory (col. 9, lines 30-50)

The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Vardi et al.'s system which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 17, 19, 39-44, 46-52, 54-61 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vardi et al. (6,325,826). Although, Vardi et al. did not expressly disclose movable members are the self-expandable structures, Vardi et al. disclose the stent being self-expanding to conform to the shape of the vessel in which they are deployed. Thus, movable members are inherently self-expanding or obvious to one having ordinary skill in the art to make them self-expanding so that the stent can be self-dilated.

It also well known in the art to deliver a self-expanding by an outer sheath in combination with dilate balloon so that the balloon and the outer sheath can hold the stent in stationary position while delivering as well as to maximize the dilation of the self-stent at a treated site. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the balloon 25 for delivering stent being made from self-expanding material having plurality movable member 38. Doing so would meet all the limitations of the claims.

Allowable Subject Matter

6. Claims 45 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

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limitations of the base claim and any intervening claims. The prior art fails to disclose the a bulge region positioned on an exterior surface of a body region of a balloon and between proximal and distal ends of the body region.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

August 7, 2006